

**IN THE DRAWINGS:**

The drawings were objected to by the Examiner. Replacement drawings are attached hereto.

## REMARKS

With this response, Claims 1-28 are pending in the present application. Claim 29 has been canceled to facilitate allowance.

The drawings were objected to by the Examiner. Replacement sheets are attached.

Claims 2 and 17 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1-8, 12-19 and 22-26 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,861,195 to Bhave et al. Claims 9-11, 20-21 and 27-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro et al. Claim 29 was rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. in view of Lee or Valentini.

### **The Claims, as Previously Amended, Overcome the 35 U.S.C. §112 Rejection**

The Examiner again noted the use of uncapitalized trademarks in the specification. Applicant has searched the complete specification and does not believe any current, federally registered trademarks remain uncapitalized in the specification. In reviewing the specification, however, Applicant did find various other typographical errors, and has corrected those by amending ¶¶ 0015, 0017, 0030, 0039, 0041-0046.

Claims 2 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Final Office Action states that support in the specification as originally filed could not be found for the limitation “translating the medical device relative to the coating head.” As noted in Applicant’s previous response, support for the previously-amended language can be found at least in ¶¶ 0027 and 0037 of the application. Paragraph 0027 discloses “medical device 11 [that] can be translated in both the X and Y

Cartesian planes under the outlet orifice 22 of the coating head ... . Alternatively, the coating head 20 can translate relative to the medical device.” Paragraph 0037 similarly discloses “holder 40 [holding the medical device], slide coating head 60, or both can be translated ... or rotated relative to each other ...” Therefore, the disclosure provides support for at least translating the medical device relative to the coating head, and vice-versa. The previously-amended language is not new matter and the Applicant respectfully requests withdrawal of this rejection.

**The Claims, as Previously Amended, are Patentable Over Bhave**

Claims 1-8, 12-19 and 22-26 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,861,195 to Bhave et al. Independent claims 1 and 16 were previously amended in the Response to September 28, 2005 Office Action to recite the “implantable medical device” limitation in both the preamble and body of the claim. Applicant argued then and continues to argue that Bhave’s coated “X-ray film” products are not implantable medical devices “used, at least in part, to penetrate the body of a patient.” See Application, ¶ 0041.

Bhave generally regards creating imaging products, such as photographic film, by coating the film with various photographic and thermographic layers and emulsifiers. See Bhave, Abstract; Examples at cols. 17-25; col. 1:33-36. Bhave’s examples disclose coating photographic film to make photothermographic imaging product made from coatings including photothermographic emulsion layers, photosensitized silver soap and resins. *Id.* The device in Bhave attempts to minimize defects such as “streaking” in the photographic film imaging products when coating multiple layers on the photothermographic film, which lead to poor photographic imaging quality. See Bhave, col. 2:8-10.

In contrast to the teachings of Bhavé, the current invention, as recited in claims 1 and 16 is directed to a medical device designed to be implanted into the body of a patient, having nothing to do with the photographic or photothermographic products. The claimed invention relates to therapeutic or other coatings for implantable medical devices and allows for a cost-effective method for applying multiple layers of different coatings without requiring appropriate drying time between coating steps.

The Office Action asserts that “implantable” reflects “merely intended use of the medical device, and no actual implantation has occurred.” Previously amended claims 1 and 16 recite the “implantable medical device” limitation in both the preamble and the body of the claim. Terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. *See, e.g., Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 U.S.P.Q.2d 1962, 1966 (Fed. Cir. 1989). The determination on whether the preamble includes limitations “can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” *Id.* Further, if the recited purpose or intended use results in a difference between the claimed invention and the prior art, the recitation serves to limit the claim. *See, e.g., In re Otto*, 312 F.2d 937, 938, 136 U.S.P.Q. 458, 459 (C.C.P.A. 1963).

Here, Applicant’s recitation of an “implantable medical device” limits the structure of the claimed invention, and thus should be treated as a claim limitation with due patentable weight accorded to it. *See Glass Works*, 868 F.2d at 1257. The term “implantable” limits the structure of the invention to those structures “which are used, at least in part, to penetrate the body of a patient.” *See Application*, ¶ 0041. The specification provides non-limiting examples of such implantable devices at paragraph 0041, such as a vascular stent, aneurysm filling coils, blood clot

filters and soft tissue clips, among others. Such implantable medical device structures are known by a person of ordinary skill in the art as possessing unique structures and properties that facilitate implantation of the medical device into body tissue, such as, for example, size constraints and biocompatibility. Thus, recitation of the term “implantable” limits the structure of the claimed invention within the field of medical devices and the term should be accorded patentable weight.

Further, Applicant’s recitation of “implantable medical device” also recognizes the difference between the claimed invention and Bhave, and thus should be treated as a claim limitation with patentable weight for this reason as well. *See In re Otto*, 312 F.2d at 938. Recitation of “implantable” recognizes and emphasizes the difference between the claimed invention and Bhave, which discloses photothermographic coating applications for non-implantable photographic film. Thus, the term “implantable” should be accorded patentable weight as a claim limitation, and not merely as an “intended use.”

Finally, to the extent “implantable” is considered merely functional language, Applicant respectfully submits that disregarding the implantable nature of the medical device is contrary to law:

[A]t times an Examiner may refuse to provide patentable weight to functional limitations, essentially ignoring many of the limitations of the claim. In this instance, the Examiner may remove the most important features when determining whether the claim is anticipated. Applicants should be aware, however, that an Examiner is not permitted to dissect the claim and remove the functional limitations before determining anticipation.

Patent Prosecution: Practice & Procedure Before the U.S. Patent Office, I. Donner (2d ed.1999), p. 478 (emphasis supplied). According to precedent, to the extent “implantable” may be regarded as functional language, it should be given patentable weight. *See In re Land*, 368 F.2d 866 (C.C.P.A. 1966); *In re Swinehart*, 439 F.2d 210 (C.C.P.A. 1971).

Accordingly, Applicant requests reconsideration of the rejection and again submits that claims 1-8, 12-19 and 22-26 are patentable over the Bhavé reference.

### **The Claims are Patentably Distinct Over Castro**

Claims 9-11, 20-21 and 27-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro et al. Applicant respectfully maintains that the claims are patentable over Castro for several reasons.

First, as an initial matter, Applicant asserts that dependent claims 9-11 and 20-21 are allowable over Castro because they depend from independent claims that were not rejected under Castro. The Office Action did not reject independent claims 1 and 16 over the Castro reference, so the dependent claims 9-11 and 20-21 are also allowable over Castro.

Second, claims 9-11, 20-21 and 27-28 are patentably distinct over Castro because Castro does not suggest or disclose at least the limitation of “an inlet and an outlet orifice” of the coating head, or the steps of “flowing a coating material into the inlet” and “dispelling the coating material through the outlet orifice onto the slide surface” of the coating head, as claimed in independent claims 1, 16 and 27 (from which the rejected claims depend).

It is the Examiner’s position that, in Castro, “composition 10 gravitationally slides down the inside surface of dispenser 22 to nozzle 26, thus meeting the limitations of dispelling onto a slide surface.” It is unclear whether the Examiner considers the inner wall of nozzle 26, the inner wall of dispenser 22, or both, a slide surface. Regardless, the device in Castro does not disclose “an inlet and an outlet orifice” of the coating head or the steps of “flowing a coating material into the inlet” and “dispelling the coating material through the outlet orifice onto the slide surface.” To the extent Castro provides a slide surface, it does not disclose an outlet orifice

that dispels the coating material onto any surface adapted to facilitate gravitational fluid flow, nor does it disclose an inlet orifice through which coating material is fluidly communicated to the outlet orifice. Furthermore, there is no suggestion or motivation provided in Castro to modify the syringe-type dispenser of Castro to add these structural features of an inlet and outlet, nor does the Office Action point to any. Accordingly, Applicant respectfully submits that claims 9-11, 20-21 and 27-28 are patentable over the Castro reference for this reason as well.

Third, Applicant asserts that claims 20 and 21 are allowable for the independent reason that the device in Castro does not disclose the limitation of a “second slide surface” adjacent to the first slide surface, and the step of “flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material.” Even if Castro were considered to disclose any slide surface (a point with which Applicant disagrees), it does not disclose a plurality of slide surfaces positioned to form a multi-layer coating material. Accordingly, Applicant respectfully submits that claims 20 and 21 are independently patentable over the Castro reference for this reason as well.

**Claim 29 is Canceled.**

Claim 29 was rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro et al. taken in view of Lee or Valentini. Applicant has canceled claim 29 to facilitate allowance.

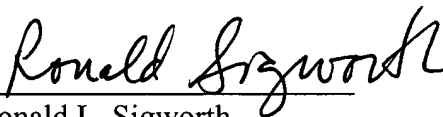
**CONCLUSION**

In view of the preceding remarks, the Applicant respectfully asserts that each of the pending claims are in condition for allowance and, therefore, requests reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Kenyon & Kenyon Deposit Account No. 11-0600 for any applicable fee.

Should the Examiner require any additional information regarding this Response, the Examiner is invited to contact the undersigned at (202) 220-4200.

Respectfully submitted,



Ronald L. Sigworth  
Reg. No. 53,592

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KENYON & KENYON  
1500 K Street, N.W., Suite 700  
Washington, D.C. 20005  
(202) 220 - 4200 (telephone)  
(202) 220 - 4201 (facsimile)  
RLS/bep